K136336
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MAR 28 2013

Eizo Nanao Corporation, 153 Shimokashiwano, Hakusan, Ishikawa
924-8566 Japan

Name Hiroaki Hashimoto
Department Medical System Standards

Telephone +81 (76) 274-2468
Fax +81 (76) 274-2484
E-Mail hiro@nanao.co.jp

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

510(k) Summary (in accordance with 21 CFR 807.92)

1. Company

Eizo Nanao Corporation
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan
Tel: +81 (76) 274-2468
Fax: +81 (76) 274-2484

2. Contact Person

Hiroaki Hashimoto

3. Date of Summary

February 6th, 2013

4. Device Information

- Trade Name/Model: RadiForce GX540
- Common Name: 5MP Monochrome LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device

- 5MP Monochrome LCD Monitor, RadiForce GX530 (K112354)

6. Device Description

RadiForce GX540 is a monochrome LCD monitor for viewing medical images including those of mammography. The monochrome panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 2,048 x 2,560 pixels (5MP) with a pixel pitch of 0.165 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

Model variations with cosmetic differences are distinguished by characters attached to the name of the base model "GX540" such as "GX540-CLAR", a model whose backlight is Clear Base with an Anti-Reflective coating on the screen surface although the hardware design, components and labeling remain unchanged.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce GX540 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS is included in this 510(k) submission as an accessory to the RadiForce GX540.

7. Intended Use

This product is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

8. Comparison of Technological Characteristics

The comparison table below enumerates information derived from the product literature of the each device and different technological characteristics are discussed in it:

Attributes	Eizo RadiForce GX540	Eizo RadiForce GX530	Explanation of Differences
Display Performance/Specifications			
Screen technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
Viewing angle (H, V)	H: 176°, V: 176° @ CR≥10	H: 170°, V: 170° @ CR≥50	Eizo uses typical data for very low contrast provided by the panel manufacturers
Active screen size	337.9 mm x 422.4 mm	337.9 mm x 422.4 mm	-
Resolution	5MP (2,048 x 2,560)	5MP (2,048 x 2,560)	
Aspect ratio	4:5	4:5	-
Pixel pitch	0.165 mm x 0.165 mm	0.165 mm x 0.165 mm	-
Maximum luminance	1,200 cd/m^2	1,200 cd/m^2	-

DICOM calibrated luminance	500 cd/m^2	500 cd/m^2	-
Contrast ratio	1200:1	1200:1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	LED	CCFL	See main text.
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
Video Signal Input			
Input video signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1 , DisplayPort x 1	-
Scanning Frequency (H, V)	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	-
Power Related Specifications			
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	108 W / Less than 0.7 W	130 W / Less than 2.5 W	The proposed device consumes less power than the predicate device.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	-
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	388 x 496 x 99 mm	388 x 496 x 99 mm	-

For the substantial equivalence determination, only the difference of the backlights needs further evidences by performance testing.

9. Performance Testing

The following bench tests were performed on the RadiForce GX540:

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline.
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance
- Measurement of display reflections including specular, diffuse and haze components
- Measurement of small-spot contrast ratio
- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of pixel aperture ratio
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Performance data on luminance stability
- The maximum number allowed for each type of pixel defects/faults agreed with the manufacturer from which Eizo buys the LCD panels for RadiForce GX540

None of the tests revealed behaviors inconsistent with the expected performance.

No animal or clinical testing was performed on the RadiForce GX540.

10. Conclusion

The 5MP Monochrome LCD Monitor, RadiForce GX540 is substantially equivalent to the predicate device with respect to technical characteristics, performance, application and intended use. The specifications of the primary component employed by the proposed device are the same as those of the predicate device and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Eizo Nanao Corporation
% Mr. Hiroaki Hashimoto
Manager of Medical System Standards Division
153 Shimokashiwano, Hakusan. Ishikawa 924-8566
JAPAN

Re: K130336
Trade/Device Name: 5MP Monochrome LCD Monitor, RadiForce GX540
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2013
Received: February 11, 2013

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

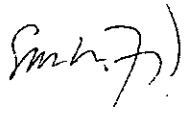
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130336

Device Name: 5MP Monochrome LCD Monitor, RadiForce GX540

Indications for Use:

This product is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130336